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AESCULAP®

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510(k) Summary of Safety and Effectiveness in Accordance with SMDA of 1990

Aesculap Angled Neuroendoscopes

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Product: Aesculap Angled Neuroendoscopes

Common Name: Neuroendoscopes

Intended Use

Aesculap's Angled Neuroendoscopes are intended for use in visualization of ventricles and structures within the brain.

Technological Characteristics

The Angled Neuroendoscopes presented in this submission are designed to provide visual orientation and illumination in endoscopy-assisted microsurgery of the brain.

These rigid, rod-lens neuroendoscopes are 4.0mm in diameter, 160mm in working length, with either 0°, 30° or 70° direction of view. The lens eyepiece is angled at 90° to allow an unobstructed view when used in conjunction with a surgical microscope. The angled neuroendoscopes are reusable devices composed primarily of stainless steel.

An optional holding device, Aesculap's Flexible Titanium Support Arm (FF169R), can be used to position and hold the neuroendoscope. With use of the flexible support arm, the surgeon can freely operate with both hands.

Performance Standards

No applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, Aesculap's Neuroendoscopes comply with the requirements of IEC 601-1 (Medical electrical equipment, Part 1: General Requirements for Safety) and IEC 601-2-18 (Medical electrical equipment, Part 2: Particular requirements for the safety of endoscopic equipment.) The Angled Neuroendoscopes have undergone Thermal Safety testing to ensure they are safe for their intended use.

Sterilization

The Angled Neuroendoscopes are provided non-sterile and must be sterilized prior to use. The devices may be sterilized by steam sterilization.

Substantial Equivalence

Aesculap's Angled neuroendoscopes shares similar features and function with corresponding devices distributed by:

- Aesculap (Neuroendoscope, Endoscopes)
- Codman (Neuroendoscopes)